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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,414	03/10/2006	Frank Theobald	R04209US (#90568)	3449
28672 7590 09/13/2007 D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			EXAMINER MI, QIUWEN	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/571,414

Applicant(s)

THEOBALD ET AL.

Examiner

Qiuwen Mi

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 and 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/10/06, 2/1/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-12, and 25-33 in the reply filed on 8/8/07 is acknowledged. The traversal is on the ground(s) that the cited reference of Bessette et al does not teach the technical feature of the current invention. This is found persuasive, however, since Group I does not require the existence of 0.1-1% Al-acetylacetonate (claim 22), 20-35% of anhydrous glycerol, and 15-25% propylene glycol (claim 23) in Group II, therefore, there is no special technical feature in the application. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1., and therefore lack of unity of invention exists.

The requirement is still deemed proper and is therefore made FINAL.

Applicant requested to examine recipe 1 on paragraph 46 of the specification, however, the recipe is not in the claims. Furthermore, the recipe contains components Durotak®387-2054, and Atoms ® 300 which have trademark names that are not searchable.

Claims 13-22, and 34-44 are withdrawn from further consideration as being drawn to nonelected inventions.

Claims Pending

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Claims 1-44 are pending. Claims 13-22, and 34-44 are withdrawn as they are directed toward non-elected invention groups. Claims 1-12, and 25-33 are examined on the merits.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-11, 25-27, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al (US 6,090,403).

Block et al teaches a skin patch for the relief of colds (claim 1). The patch includes an underlying layer of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied (col 5, lines 4-10). The patch is capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch (col 2, lines 52-60). The expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also helps to prolong the useful life of the product (col 2, lines 25-30). A variety of well known therapeutic agents that have a decongestant or analgesic action can be employed, examples include oil of menthol, camphor etc (col 2, lines 60-65). A hydrophobic vehicle comprises a pressure-sensitive adhesive matrix (col 3, lines 18-21). Other adhesives such as

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acrylic polymeric adhesives (a type of polyacrylates), and vinyl acetate copolymers (the same as polyvinyl acetate), can be used (col 3, lines 23-26). The skin patch includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya (a type of gum, hydrophile polymer, having adsorbent effect), carboxymethyl cellulose (cellulose derivative), polyacrylamide, and polyacrylic acid (claim 10). The patch also includes a humectant (a type of moisturizer, adjuvant) comprising a polyhydric alcohol (claim 6), and the antitussive is camphor or menthol (claim 40).

Block et al do not teach the specific claimed amounts of the followings: water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, and adjuvants.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Block et al, since Block et al yielded beneficial results in skin patch, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, and adjuvants, etc, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 1-11, 25-29, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Block et al (US 6,090,403), and Kelley (US 2003/0167556).

Block et al teaches a skin patch for the relief of colds (claim 1). The patch includes an underlying layer of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied (col 5, lines 4-10). The patch is capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch (col 2, lines 52-60). The expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also helps to prolong the useful life of the product (col 2, lines 25-30). A variety of well known therapeutic agents that have a decongestant or analgesic action can be employed, examples include oil of menthol, camphor etc (col 2, lines 60-65). A hydrophobic vehicle comprises a pressure-sensitive adhesive matrix (col 3, lines 18-21). Other adhesives such as acrylic polymeric adhesives (a type of polyacrylates), and vinyl acetate copolymers (the same as polyvinyl acetate), can be used (col 3, lines 23-26). The skin patch includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya (a type of gum, hydrophile polymer, having adsorbent effect), carboxymethyl cellulose (cellulose derivative), polyacrylamide, and polyacrylic acid (claim 10). The patch also includes a humectant (a type of moisturizer, adjuvant) comprising a polyhydric alcohol (claim 6), and the antitussive is camphor or menthol (claim 40).

Block et al do not teach the adsorbent cyclodextrin, emulsifier sodium lauryl sulfate or any claimed amounts of the followings: water content of the matrix, the claimed adsorbent, or emulsifying substance, detachable protective layer, or the amount of hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance, and moisturizers.

Kelley teaches methods and devices for transdermal delivery (see Title) using a skin patch (see Abstract). Kelley suggests using membrane penetration-enhancing agents such as cyclodextrin [0148] and topical absorption enhancing agents such as surface active agent sodium lauryl sulfate, or Tween 80 [0149] (inherently has emulsifying action).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for skin patch. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims,

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in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Block et al and Kelley, since both of them teach compositions for skin patch individually in the art. Since both the compositions yielded beneficial results in skin patch, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance, and moisturizers, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 1-11, and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Block et al (US 6,090,403), Kelley (US 2003/0167556), and Kamiya et al (US 5,780,047).

Block et al teaches a skin patch for the relief of colds (claim 1). The patch includes an underlying layer of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied (col 5, lines 4-10). The patch is capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch (col 2, lines 52-60). The expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant

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agent. It also helps to prolong the useful life of the product (col 2, lines 25-30). A variety of well known therapeutic agents that have a decongestant or analgesic action can be employed, examples include oil of menthol, camphor etc (col 2, lines 60-65). A hydrophobic vehicle comprises a pressure-sensitive adhesive matrix (col 3, lines 18-21). Other adhesives such as acrylic polymeric adhesives (a type of polyacrylates), and vinyl acetate copolymers (the same as polyvinyl acetate), can be used (col 3, lines 23-26). The skin patch includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya (a type of gum, hydrophile polymer, having adsorbent effect), carboxymethyl cellulose (cellulose derivative), polyacrylamide, and polyacrylic acid (claim 10). The patch also includes a humectant (a type of moisturizer, adjuvant) comprising a polyhydric alcohol (claim 6), and the antitussive is camphor or menthol (claim 40).

Block et al do not teach the adsorbent cyclodextrin, emulsifying substance sodium lauryl sulfate, essential oil pine oil or any claimed amounts of the followings: water content of the matrix, adsorbent cyclodextrin, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance, and moisturizers.

Kelley teaches methods and devices for transdermal delivery (see Title) using a skin patch (see Abstract). Kelley suggests using membrane penetration-enhancing agents such as cyclodextrin [0148] and topical absorption enhancing agents such as surface active agent sodium lauryl sulfate, or Tween 80 [0149] (inherently has emulsifying action).

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Kamiya et al teach a patch that is convenient in handling and achieves high merit (see Abstract). Kamiya et al teach that the patch is applied on a human skin (thus skin patch), and exerts medicinal effects on painful stiff neck and shoulder (col 2, lines 22-30). Kamiya et al also suggest that the patch may contain essential oils and perfumed oils such as pine oil etc (col 7, lines 27-34).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for skin patch. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Block et al, Kelley, and Kamiya et al since all of them teach compositions for skin patch individually in the art. Since all of the compositions yielded beneficial results in skin patch, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance, and moisturizers, etc, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 1-12, and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Block et al (US 6,090,403), Kamiya et al (US 5,780,047), Kelley (US 2003/0167556), and Merkle et al (US 5,527,536).

Block et al teaches a skin patch for the relief of colds (claim 1). The patch includes an underlying layer of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied (col 5, lines 4-10). The patch is capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch (col 2, lines 52-60). The expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also helps to prolong the useful life of the product (col 2, lines 25-30). A variety of well known therapeutic agents that have a decongestant or analgesic action can be employed,

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examples include oil of menthol, camphor etc (col 2, lines 60-65). A hydrophobic vehicle comprises a pressure-sensitive adhesive matrix (col 3, lines 18-21). Other adhesives such as acrylic polymeric adhesives (a type of polyacrylates), and vinyl acetate copolymers (the same as polyvinyl acetate), can be used (col 3, lines 23-26). The skin patch includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya (a type of gum, hydrophile polymer, having adsorbent effect), carboxymethyl cellulose (cellulose derivative), polyacrylamide, and polyacrylic acid (claim 10). The patch also includes a humectant (a type of moisturizer, adjuvant) comprising a polyhydric alcohol (claim 6), and the antitussive is camphor or menthol (claim 40).

Block et al do not teach the adsorbent cyclodextrin, emulsifying substance sodium lauryl sulfate, detachable protective layer, essential oil pine oil or any claimed amounts of the followings: water content of the matrix, adsorbent cyclodextrin, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance, and moisturizers.

Kamiya et al teach a patch that is convenient in handling and achieves high merit (see Abstract). Kamiya et al teach that the patch is applied on a human skin (thus skin patch), and exerts medicinal effects on painful stiff neck and shoulder (col 2, lines 22-30). Kamiya et al also suggest that the patch may contain essential oils and perfumed oils such as pine oil etc (col 7, lines 27-34).

Kelley teaches methods and devices for transdermal delivery (see Title) using a skin patch (see Abstract). Kelley suggests using membrane penetration-enhancing agents such as

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cyclodextrin [0148] and topical absorption enhancing agents such as surface active agent sodium lauryl sulfate, or Tween 80 [0149] (inherently has emulsifying action).

Merkle et al teach a patch for controlled release of readily available volatile active substances to the skin (thus a skin patch), the patch comprising a back layer, and bonded to it, a water-insoluble adhesive film consisting of a pressure-sensitive fusion adhesive, plus a detachable film covering the adhesive film (see Abstract). Merkle et al also teach the skin patch is covered with a protective film, which is removed by peeling it off from the reservoir layer before the use of the patch, that is before application of the patch on the skin (col 1, lines 15-21). Merkle et al further teach that the patch is characterized in that the pressure-sensitive fusion adhesive contains a triple-block copolymer of polystyrene block copoly (ethylene/butylenes) block polystyrene (synthetic rubbers) at a concentration of 10-80% by wt., and an active substance which, at the temperature at which the adhesive bonds, is a readily volatile liquid, and which is present at a concentration of 2.5 to 25% by wt (see Abstract).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

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Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Block et al, Kamiya et al, Kelley, and Merkle et al since all of them teach compositions for skin patch individually in the art. Since all the compositions yielded beneficial results in skin patch, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance, and moisturizers, etc, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

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Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/
Patricia Leith
Primary Examiner
AU 1655